

REMARKS

The Amendments

Support for the amendments to claims 1-10 is inherent in the original disclosure. The claims are amended only to better conform them to U.S. practice and add suitable dependent claims.

Support for new claim 11 can be found in original claim 4, for example. Support for new claims 12 and 13 can be found in original claim 6, for example. Support for new claims 14-16 can be found in original claim 9, for example. Support for new claims 17-25 can be found in original claims 7 and 8, for example. Support for new claim 26 can be found in original claim 10, for example.

The Rejection under 35 U.S.C. §112, second paragraph

The rejection of claims under 35 U.S.C. §112, second paragraph, is believed to be moot in view of the current claims.

The Rejection under 35 U.S.C. §103

The rejection of claims 1-10 under 35 U.S.C. §103 as being unpatentable over Li (WO96/40087) in view of Lipp (U.S. Patent No. 5,676,968) is respectfully traversed.

As the examiner notes neither Li nor Lipp disclose use of the specific gestagen of the claim in a transdermal matrix. Moreover, the mere fact that these references employ gestagens does not render the claims obvious.

The compound contained within applicant's transdermal matrix system is a highly potent gestagen when in dissolved form and has a surprisingly high solubility of up to about 20%. Extraordinarily high transdermal flows can be achieved (See page 6, paragraph 5). Such a combination of properties is unique for gestagens.


Gestagens previously used for transdermal systems generally have relatively low solubilities in the matrices used or have higher solubilities but then have low potency. For example, gestodene or levonorgestral have low solubilities of about 1 %. Therefore a crystal free transdermal system can be produced only if the content of the gestagen in the matrix does not significantly exceed the relatively low saturation concentration (See page 2, line 17-23 of the specification). Norethisterone has high matrix solubility (about 7 %) yet low gestagenic potency.

Li and Lipp are the same. In fact for Lipp, the active ingredients are disclosed as preferably poorly soluble or insoluble in usual adhesive systems and which crystallize well, including gestagens. This is opposite to and teaches away from the active ingredient of the invention (See col. 2, lines 48-59). As for Li, he does not teach use of gestagens in general but only mentions two specific ones in claim 7, not suggesting any other gestagens can be used

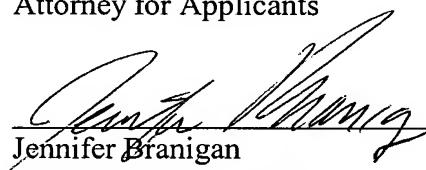
Thus, the rejection under 35 U.S.C. §103 should be withdrawn.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

Respectfully submitted,



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